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TITLE: Genetic Epidemiology of *in situ* Breast Cancer

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CONTRACTING ORGANIZATION: Yale University
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This four-year project will define risk factors associated with BCIS through the mechanism of a case/control study. The study population will include approximately 800 cases of female breast carcinoma in situ and 800 age-matched female controls selected from the population of the state of Connecticut. At the end of year two, 652 eligible cases and 632 eligible controls have been identified. Physicians have consented for 95% of eligible cases. Ninety two percent of contacted eligible cases and 80% of contacted eligible controls have agreed to participate in telephone interviews which collect information concerning family history of cancer, pregnancy and menstrual history, hormone replacement therapy, oral contraceptive use, fertility drug use, as well as sociodemographic variables. In addition, a tissue repository consisting of paraffin-embedded tumor tissue collected from each of the cases will be formed. At present only two percent of contacted eligible cases have refused to release slides and/or blocks to our study. The expression of two of the most frequently reported oncogenes associated with invasive breast cancer, p53 and c-erbB-2, as well as ER and PR will be examined in these BCIS cases for the first time in a population-based series.

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E B Clarke 12/13/96

PI - Signature Date

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# THE GENETIC EPIDEMIOLOGY OF BREAST CARCINOMA IN SITU

## 5. INTRODUCTION

Breast cancer remains one of the most important health care issues of the 20th century. Despite a wealth of studies on the topic, the current literature provides little information regarding the nature of the epidemiologic risk factors or clinical characteristics of breast tumors which are classified as non-invasive, i.e., breast carcinoma in situ (BCIS). As screening efforts throughout the United States have increased, so has the number of women diagnosed with BCIS, with up to 20% of screened patients diagnosed with this lesion. The identification of risk factors associated with the development of BCIS is especially important, particularly in light of the fact that in the coming century up to one in fifty women in the United States will be diagnosed with this tumor during her lifetime. This four-year project will define risk factors associated with BCIS through the mechanism of a case/control study. The study population will include approximately 800 cases of female breast carcinoma in situ and 800 age-matched female controls selected from the population of the state of Connecticut over a 3.5 year data collection period. Cases will be between the age of 20 and 84 years at time of diagnosis. The controls will be frequency matched to the cases by five year age intervals. Telephone interviews will be conducted with the study subjects and will collect information concerning family history of cancer, pregnancy and menstrual history, hormone replacement therapy, oral contraceptive use, fertility drug use, as well as sociodemographic variables. In addition, a tissue repository consisting of paraffin-embedded tumor tissue collected from each of the cases will be formed. The expression of two of the most frequently reported oncogenes associated with invasive breast cancer, p53 and c-erbB-2, will be examined in BCIS cases for the first time in a population-based series.

The goals of this study are as follows:

1. To determine whether there is an association between a family history of breast and/or ovarian cancer and the development of breast carcinoma in situ (BCIS).

2. To determine whether there is an association between additional epidemiologic risk factors, including those traditionally associated with invasive breast carcinoma such as age at menarche, age at first birth, and oral contraceptive use and the development of BCIS.

3. To collect paraffin-embedded tumor tissue for each of the BCIS cases.

4. To test for the presence of p53 and c-erbB-2 protein expression as well as estrogen and

progesterone receptor expression using the methods of immunohistochemistry in the paraffin-embedded tumor tissue.

5. To examine the association between p53 and/or c-erbB-2 expression in BCIS tumors with clinical and epidemiologic variables including grade and family history of breast cancer.

6. To develop risk prediction models to be used in defining screening guidelines for women not yet diagnosed with BCIS.

## Specific Location of Study

Drs. Claus and Holford have offices located in the Department of Epidemiology and Public Health. Dr. Carter's office and laboratory is located within the Pathology Department. The office of Dr. Meredith Stowe, Project Director, and Ms. Judie Fine, Director, Rapid Case Ascertainment Shared Resource, is located at 200 College Street, New Haven, CT.

## 6. BODY

### RESEARCH PLAN

The cases are ascertained through the Rapid Case Ascertainment (RCA) Shared Resource of the Yale Cancer Center, under the direction of Ms. Judie Fine. The physicians of each eligible case are identified by Ms. Fine. The names of patients and physicians are given to Dr. Meredith Stowe, the project director, by Ms. Fine. A letter signed by Drs. Claus and Stowe is sent to the physicians requesting permission to send a letter of introduction to the case.

Proto-controls are identified by Northeast Research in Orono, Maine through the mechanism of random-digit dialing. Female residents of the state of Connecticut aged 20-84 who are served by a telephone are eligible.

Those cases approved for contact by their physicians are sent a letter of introduction from Drs. Claus and Stowe explaining the project. Controls receive a similar letter. Informed consent forms accompany the letter of introduction and study subjects are asked to return them via the stamped, addressed envelope provided. Approximately 1-2 weeks later an interviewer (either Ms. Sheila Griffin or Ms. Marjorie Jasmin) contacts the potential study subject by telephone. If the potential study subject decides to participate, the interviewer administers the questionnaire over the telephone at the patient's convenience after verbal consent has been given for the interview. Subjects who agree to be interviewed are sent an oral contraceptive picture booklet with an accompanying letter. Subjects are interviewed for approximately 30-45 minutes. Interviews of

women with particularly complex family or medical histories may take somewhat longer. The questionnaire includes questions on family history of cancer, pregnancy and menstrual history, oral contraceptive and other exogenous hormone history, medical history, socioeconomic status, as well as alcohol and tobacco use.

We plan to collect pathology slides and histologic specimens in the form of paraffin-embedded tumor tissue. Cases who agree to allow us to retrieve paraffin-embedded blocks are sent an authorization of health information form which we ask them to return via mail. RCA will request and courier slides and paraffin-blocks from each of the pathology departments as well as return the slides and blocks after the laboratory analyses are completed. The blocks are returned to the various hospitals after sufficient material has been removed from them. Alternatively, hospitals may choose to cut material from the blocks rather than send the block itself. The slides will be quickly returned after our pathologist, Dr. Darryl Carter, has reviewed them to confirm the diagnosis and perform a uniform histologic review.

Medical records may need to be reviewed to provide details requested in the questionnaire regarding dates of diagnoses or pathologic details of diagnosis. In particular, pathology data are useful in identifying tumor blocks most likely to contain tumor. A stamped, addressed envelope is provided for study subjects so that they may return the authorization for release of health information (for review of medical records and retrieval of paraffin-blocks) via mail. Dr Stowe telephones study participants who do not return the form to encourage them to do so. Replacement forms are sent to women who misplace the original form.

A small number of cases diagnosed at Yale-New Haven Hospital or who live in Tolland County will be eligible for a second study conducted by Dr. Tongzhang Zheng of the Department of Epidemiology and Public Health. Drs. Claus and Zheng will send a joint letter to the physicians as well as a joint letter of introduction to the cases. Furthermore, Drs. Claus and Zheng will alternate their initial contact with these women and work together to make certain that these patients and their physicians are not overburdened relative to study participation.

## YEARLY REPORT

The personnel on the project have remained stable, with Drs. Claus and Holford continuing to act as Principal Investigator and Co-Investigator, respectively. Dr. Darryl Carter continues as the study pathologist and Dr. Meredith Stowe as the project director. Our two interviewers, Ms. Sheila Griffin and Ms. Marjorie Jasmin, continue to work with us and Ms. Judie Fine remains as the director of the Rapid Case Ascertainment Service.

The primary goal of year two was the identification, consent, and interview of cases and controls. The details of this process are presented in Table 1. At this point in time, 822 cases have been identified for the study through the services of the Rapid Case Ascertainment Service.

Six hundred and fifty-two of these cases have been verified to be eligible, 79 to be ineligible, and 91 are pending eligibility review. Six hundred forty-three controls have been identified by Northeast Research (see Appendix A for yearly update), 632 of whom remain as verified controls. Our physician consent rate for cases has been quite high with 95% of cases having a consenting physician. Our case and control response rates have also been extremely encouraging. Among eligible cases who have been contacted by our study, 92% have agreed to participate in the interview portion of the study. Among eligible controls who have been contacted by our study, 80% have agreed to participate in the interview portion of the study.

In addition to the interview portion of the study, we have embarked upon the paraffin block collection portion of the study. This aspect of the study entails obtaining written permission from cases to retrieve the blocks and then physical retrieval of the blocks from various hospitals for laboratory analysis. A summary of case consent rates for this portion of the study is shown in Table 2. At present, only two percent of interviewed cases have actively refused to allow us to retrieve slides/blocks. The remainder have verbally agreed to allow us to retrieve slides and blocks. Approximately 60% of all cases and 73% of interviewed cases have returned the permission slip. We are now working on mailing a second permission form and retelephoning women regarding the permission form to raise our written consent levels (necessary for actual retrieval to occur) for this portion of the study. We are also now actively retrieving blocks for those women who have given permission.

Preliminary laboratory work began this year. Drs. Claus and Carter (with several additional authors) recently completed a immunohistochemical study of p53, erbB2, p-neu, ER, and PR in a series of breast carcinoma in-situ cases diagnosed from 1980 to 1993 from Yale New Haven Hospital and Bridgeport Hospital (Claus et al., submitted; DiGiovanna et al., submitted). This pilot study provided our team a means to error check and streamline the process by which the specimens from this project will be handled.

Data entry for the study is also ongoing and is completed by Ms. Wanda Carr with assistance from Ms. Leslie Holford. At present a total of 75 case interviews and 275 control interviews have been entered and error checked.

In the coming year, we will continue to identify and enroll as well as interview cases and controls. In addition the laboratory portion of the study will formally commence this year with the collection, review, and laboratory study of the paraffin blocks.

## HUMAN SUBJECTS

### Subject Population

All female Connecticut residents between the ages of 20 and 84 years at time of diagnosis

and diagnosed with breast carcinoma in situ from 9/15/94 to 3/14/98 are eligible. Cases with a previous history of breast cancer and/or a breast biopsy of unknown outcome are excluded. Data from the Connecticut Tumor Registry indicate that over the proposed 3.5 year data collection period, approximately 1100-1200 women will be diagnosed with BCIS in the state of Connecticut within the age-group of interest. From this group, we expect to interview 700-800 women. Proto-controls are randomly selected by an external firm (Northeast Research) and will consist of age-matched Connecticut female residents. We expect to identify approximately 1100-1200 proto-controls and interview 700-800 as controls.

**Risks/Benefits**

As this is primarily an interview study, we anticipate no physical risk to study subjects. However, given the serious nature of breast cancer, it is conceivable that some patients will experience some degree of psychological distress as a result of being interviewed concerning their health status. In order to minimize the occurrence of such distress, interviewers are trained to conduct interviews in a relaxed, friendly, and professional manner. Swift corrective action will be taken concerning any interviewer whose demeanor seems to have a negative effect on study participants.

There are no monetary inducements to participants in this study. The primary inducement for participants is the ability of the study to contribute to our understanding of breast cancer. This research has the potential to define modifiable risk factors associated with the development of breast cancer as well as the potential to identify currently healthy women at increased risk of this disease who might benefit from increased screening for breast cancer.

At present no adverse effects have been reported in this study. A number of positive effects have been reported, particularly to our interviewers, including the improvement of family relationships in association with the gathering of family history information. In addition, among cases, the discussion of a breast cancer diagnosis with an independent observer has proved to be helpful to a number of women.

**Protection of Subjects**

Each study subject is assigned a code number. The interview cover sheet containing identifying information is removed from the interview booklet and stored separately. All staff members are informed prior to employment and at regular intervals as to the necessity for keeping all data confidential. All written study material is stored in locked file cabinets. All histologic specimens will be stored in the laboratory of Dr. Carter.

The opinion of Dr. Carter, the study pathologist, concerning histologic specimens may in some instances differ from that of the original pathologist. If Dr. Carter interprets the woman's

cancer to be invasive rather than solely in-situ, the original pathologist and surgeon will be contacted and informed of the opinion of the study pathologist. If the original pathologist is not available, we will inform the Chair of Pathology at the appropriate hospital.

No information that identifies an individual subject will be given to third parties, including family members, unless that subject has given consent to do so. Information obtained during the study will not be placed in a subject's medical record. Publication and presentation of results will contain only aggregate data.

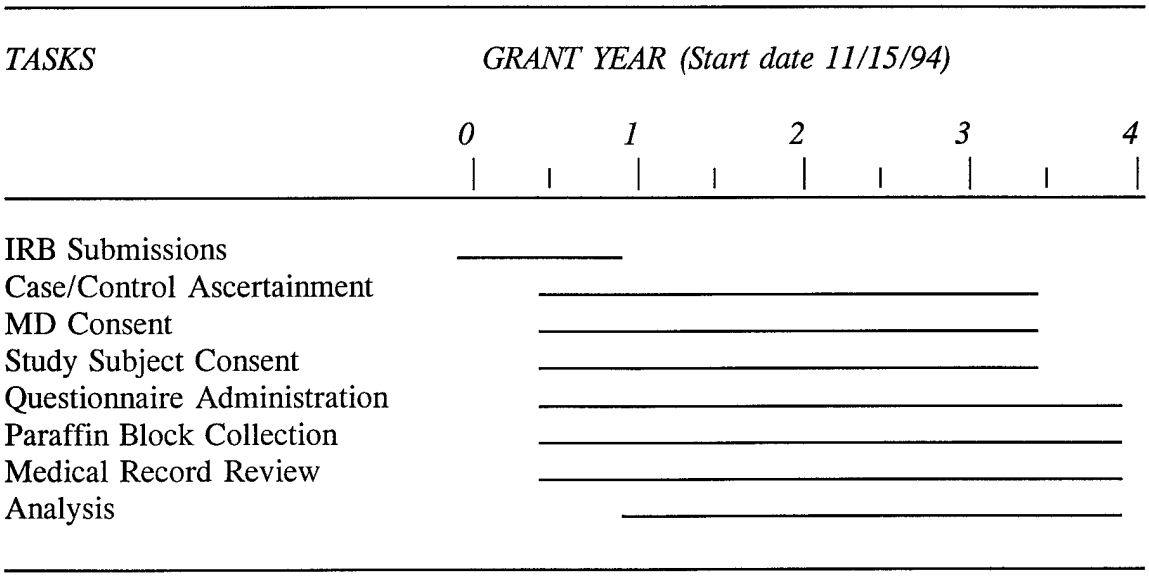
No laboratory test results on specimens will be released to the participant or her physician. This current work is in the realm of research and any results should be regarded as preliminary findings and not definitive. None of the materials collected on these patients will be used to do research unrelated to their breast cancer diagnosis.

**Human Investigation Committee Approvals**

We have had great success in obtaining the approval and participation of the state's hospitals. At present, all but four of the state's 35 hospitals are active participants. We are able to identify cases diagnosed and treated at these four hospitals via the Connecticut Tumor Registry. We are still attempting to add these four hospitals as active participants (although three are small and account for a negligible number of cases) as we will need their assistance in obtaining slides and tumor blocks for the cases from these hospitals. Overall, the response of the state's hospitals and medical personnel has been extremely positive. Most of the hospitals are now in their second year of participation with our study.

**Duration of Project**

*Figure 1. Time Table*



## REFERENCES

1. Claus EB, DiGiovanna MP, Chu P, Davison TL, Howe CL, Carter D, Stern D: The genetic epidemiology of breast carcinoma in situ: A case series from Yale-New Haven Hospital (Submitted)

2. DiGiovanna MP, Chu P, Davison TL, Howe CL, Carter D, Claus EB, Stern D: Active signaling by HER-2/neu in a subpopulation of HER-2/neu overexpressing DCIS: Clinico-pathologic correlates. (Submitted)

Table 1.

# SUMMARY OF SUBJECTS' PARTICIPATION

## November 15, 1994 - November 14, 1996

| | CASES | CONTROLS |
|---|---|---|
| IDENTIFIED | **822** | **643** |
| ELIGIBILITY | | |
| Verified Eligible | **652** | **632** |
| Verified Ineligible | 79 | 11 |
| Pending | 91 | -- |
| *Ineligible due to:* | | |
| *language* | *3* | *9* |
| *residency(not CT)* | *2* | *2* |
| *previous breast cancer* | *34* | |
| *not BCIS* | *40* | |
| MD CONSENT | | |
| Yes | **470** | --- |
| No | 24 | --- |
| Pending | 158 | --- |
| INTERVIEW STATUS | | |
| Interview Completed | **287** | **502** |
| Interview Scheduled | 55 | 6 |
| Interview Refused | 26 | 103 |
| Pending | 101 | 18 |
| Deceased | 1 | |
| Incompetent/too ill | | 2 |
| Hearing problem | | 1 |
| DATA ENTRY STATUS | | |
| Pending | 50 | 0 |
| Completed | 75 | 275 |

Table 2.

# SUMMARY OF CASE CONSENTS FOR TISSUE STUDY 12/3/96

| | Total | Release Form Received | Refused To Sign |
|---|---|---|---|
| INTERVIEW STATUS | | | |
| Release Form Mailed | 394 | 237 (60%) | 8 (2.0%) |
| Interview Completed | 322 | 235 (73%) | 8 (2.5%) |
| DATA ENTRY STATUS | | | |
| Pending | 50 | 31 (62%) | 1 (2.0%) |
| Completed | 75 | 56 (75%) | 2 (2.7%) |

All Release Forms received cover all three items: medical records, slides and blocks. (I think one person specified we may only have one small piece of her block.)

**NORTHEAST RESEARCH**
117 Mill Street
P.O. Box 9
Orono, Maine 04473
207-866-5593

NER/SAE #4139-RPT2
December 9, 1996

TO: **Elizabeth Claus, M.D., Ph.D. & Meredith Stowe, Ph.D., Yale University School of Medicine**

FR: Christine Kreider, Mary Gregg

RE: **Connecticut-wide random-digit-dial "Proto-Control Identification Survey" for "Genetic Epidemiology of In Situ Breast Cancer": Sampling Period #2-3 Report**

**Proto-Control Recruiting Status**

The identification survey for Sample Period #1 was conducted in the 5.5-month period of May 31 to November 14, 1995. We obtained final dispositions on all 1,952 random telephone numbers entered into the sample used in Sample Period #1. (See Report 1 for details.)

The indentification survey for Sample Period #2 was conducted in a 6 month period of November 6, 1995 to May 7, 1996. We obtained final dispositions on 2,964 random telephone numbers entered into the sample used in Sample Period #2. This second sample produced 321 eligible women that were willing to consider participation.

The identification survey for Sample Period #3 was conducted in a 6.5 month period, beginning May 6, 1996 and lasting until November 30, 1996. The start time of this sampling period was simultaneous with introduction of the CT-Wide Proto-Control Recruiting Survey investigating Non-Hodgkins Lymphoma, so the two could be pooled together. Final dispositions on 904 random telephone numbers entered into the sample were obtained. Sample Period #3 generated 71 proto-control subjects. Although this sampling period's final results were numerically less, we are still ahead of schedule, as shown in Table 2.

We hope to hear from your office about the age distribution of fully participating proto-controls, so we can make adjustments to our recruitment to better meet your needs (if that is necessary and possible).

**Table 1: Distribution of Proto-Controls Obtained in Sampling Periods #1-3 by Age Group**

| Age at Identification | Actually Obtained in: SP 1 | SP 2 | SP 3 | Total in 18-Mo. Period |
|---|---|---|---|---|
| 30-34 | 4 | 1 | 2 | 7 |
| 35-39 | 15 | 15 | 4 | 34 |
| 40-44 | 40 | 56 | 12 | 108 |
| 45-49 | 39 | 52 | 6 | 97 |
| 50-54 | 31 | 37 | 2 | 70 |
| 55-59 | 32 | 32 | 6 | 70 |
| 60-64 | 31 | 39 | 5 | 75 |
| 65-69 | 27 | 35 | 18 | 80 |
| 70-74 | 32 | 25 | 10 | 67 |
| 75-79 | 14 | 29 | 6 | 49 |
| Totals | 265 | 321 | 71 | 657 |

**Table 2: Totals of Proto-Controls Obtained in Sampling Periods #1-3 and Overall Design Expectations by Age Group***

| Age at Identification | Design %** | Expected an 18 MO Period | Actually Obtained in 18 Mos. | Expected in 36 MO Period |
|---|---|---|---|---|
| 30-34 | 0.74 | 4 | 7 | 9 |
| 35-39 | 5.17 | 30 | 34 | 59 |
| 40-44 | 14.76 | 85 | 108 | 170 |
| 45-49 | 14.39 | 83 | 97 | 165 |
| 50-54 | 11.07 | 64 | 70 | 127 |
| 55-59 | 11.44 | 66 | 70 | 132 |
| 60-64 | 13.28 | 76 | 75 | 153 |
| 65-69 | 12.55 | 72 | 80 | 144 |
| 70-74 | 9.23 | 53 | 67 | 106 |
| 75-79 | 7.38 | 42 | 49 | 85 |
| Totals** | 100.00 | 575 | 657 | 1,150 |

*The percentage distribution in the design is that for Connecticut in-situ breast cancer cases in 1990 provided for design purposes by Dr Claus.

**Columns may not add to exactly the totals because of rounding error.

**Survey Response Rate**

Our definition of a "response" here is that an adult contacted in the housing unit (HU) reported: (1) that one was at least one female resident belonging to an age group sought in the sample replicate; (2) that that woman spoke English well-enough to be interviewed; and (3) that the HU provided the name and mailing address of that person (or for the randomly selected age-eligible person, where two or more were residents)--in order that the Yale Medical School could send that person a letter.

The "cooperation rate," the number of positive responses ("completions") divided by the total number of HU's where we know one or more persons were gender-and-age eligible for the replicate (k/k+L+m+n).

Comments and suggestions regarding this report, our performance to date, and any future arrangements are welcome. To be certain that goals are being met, we ask for a report of your figures.

**TABLE 3: CONNECTICUT-WIDE PROTO-CONTROL IDENTIFICATION SURVEY: FINAL DISPOSITIONS OF THE PHONE NUMBERS IN THE SAMPLING PERIOD #2 SAMPLE (NOVEMBER 6, 1995 - MAY 7, 1996) AND CALCULATION OF ESTIMATED SP#2 RESPONSE RATE***

| Sample Size and its Disposition | | |
|---|---|---|
| Total number of phone numbers sampled & attempts to screen completed: | | 3091 |
| Less total could not be screened: | | 353 |
| (a) Continuous no answer, minimum of 9 calls over min. 17 days | 182 | |
| (b) Continuous (9x) answering machine, apparently a residence | 36 | |
| (c) Refusal w/o determining if age-eligible female is resident | 128 | |
| (d) Call back not reached without determination of eligibility | 7 | |
| Total screened: | | 2738 |
| Less total found not to be a year-round residence: | | 1375 |
| (e) Not in service | 764 | |
| (f) Business, modem/FAX, institution, seasonal dwelling, etc. | 611 | |
| Less total ineligible residences: | | 992 |
| (g) Ineligible: no adult female resident | 211 | |
| (h) Ineligible: no female resident of ages sought in replicate | 760 | |
| (j) Ineligible: no one of gender & age groups sought who speaks English | 21 | |

Total apparently gender & age-eligible residences: 371

(k) "Completion": Agreed to participate further ("Accept"), or to consider participating further ("Hesitant")--adult contact or proto-control provided name & address for follow-up letter 321

(L) Refused name & address of replicate-eligible persons 46

(m) Call-back appointment with eligible household never kept (minimum of 9 attempts after initial contact) 1

(n) Adult of gender and age sought resident but is mentally/physically unable to participate in survey 3

Calculation of the Estimated Proto-Subject Recruiting Survey Response Rate:

Step 1: Estimating the proportion (p) of residences the Survey attempted to reach that included one or more gender, age, and language-eligible persons:

$$p = \frac{k + L + m + n}{g + h + j + k + L + m + n} = 371/1363 = .2722$$

Step 2: Estimating the proportion of (a) that are, in fact, year-round dwellings rather than seasonal dwellings, non-subscribed numbers without intercepts, non-ringing numbers in multi-line business systems, etc. (based on recent experiments designed to provide such estimates): .28

Step 3: Estimating the p-c Identification Survey response rate [for p, see Step 1]:

$$\frac{k}{k + L + m + n + (c + d)(p) + (.28)(p)(a) + (p)(b)} = 321/431.42 = 74.4\%$$

**TABLE 4: CONNECTICUT-WIDE PROTO-CONTROL IDENTIFICATION SURVEY: FINAL DISPOSITIONS OF THE PHONE NUMBERS IN THE SAMPLING PERIOD #3 SAMPLE (MAY 6, 1996 - NOVEMBER 30, 1996) AND CALCULATION OF ESTIMATED SP#3 RESPONSE RATE***

Sample Size and its Disposition

Total number of phone numbers sampled & attempts to screen completed: 904

Less total could not be screened: 128

(a) Continuous no answer, minimum of 9 calls over min. 17 days 54
(b) Continuous (9x) answering machine, apparently a residence 8
(c) Refusal w/o determining if age-eligible female is resident 64
(d) Call back not reached without determination of eligibility 2

| | | |
|---|---|---|
| Total screened: | | 776 |
| Less total found not to be a year-round residence: | | 415 |
| (e) Not in service | 208 | |
| (f) Business, modem/FAX, institution, seasonal dwelling, etc. | 207 | |
| Less total ineligible residences: | | 268 |
| (g) Ineligible: no adult female resident | 70 | |
| (h) Ineligible: no female resident of ages sought in replicate | 188 | |
| (j) Ineligible: no one of gender & age groups sought who speaks English | 10 | |
| Total apparently gender & age-eligible residences: | | 93 |
| (k) "Completion": Agreed to participate further ("Accept"), or to consider participating further ("Hesitant")--adult contact or proto-control provided name & address for follow-up letter | 71 | |
| (L) Refused name & address of replicate-eligible persons | 20 | |
| (m) Call-back appointment with eligible household never kept (minimum of 9 attempts after initial contact) | -- | |
| (n) Adult of gender and age sought resident but is mentally/physically unable to participate in survey | 2 | |

Calculation of the Estimated Proto-Subject Recruiting Survey Response Rate:

Step 1: Estimating the proportion (p) of residences the Survey attempted to reach that included one or more gender, age, and language-eligible persons:

$$p = \frac{k + L + m + n}{g + h + j + k + L + m + n} = 93/361 = .2576$$

Step 2: Estimating the proportion of (a) that are, in fact, year-round dwellings rather than seasonal dwellings, non-subscribed numbers without intercepts, non-ringing numbers in multi-line business systems, etc. (based on recent experiments designed to provide such estimates): .28

Step 3: Estimating the p-c Identification Survey response rate [for p, see Step 1]:

$$\frac{k}{k + L + m + n + (c + d)(p) + (.28)(p)(a) + (p)(b)} = 71/115.96 = 61.2\%$$

xc: Nancy Bauer, Jenne Talbot, Kathryn Toppan, Amy Wilson, Susan Peterson, Erv Dehmlow, and Pat Hofmaster (NER/SAE)